Attachment 3: Revised 510(k) Summary

The following is a summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

Sponsor Information	
Date Prepared	August 29, 2013
Company Name	Synthes
Address	1301 Goshen Parkway West Chester, PA 19380
Contact Person	Rebecca G. Reiter
Title	Regulatory Affairs Specialist
Phone	(610) 719-1268
Fax	484-356-9682
Device Information	
Proprietary Name	Synthes 2.7mm and 3.5mm Variable Angle LCP Midfoot/Hindfoot System
Device	Plate, fixation, bone
Regulation Description	Single/multiple component metallic bone fixation appliances and accessories Screw, fixation, bone
Product Code	HRS, HWC
Submission Type	Traditional 510(k)
Regulation	888.3030, 888.3040
Device Class	Class II
Predicate Device(s):	Synthes Cortical Screws (K112583) Synthes 3.5mm Low Profile Cortical Screws (K111230) Arthrex Low Profile Screws (K103705) Synthes Locking Calcaneal Plates (K991407) Synthes 2.4/2.7 VA LCP Forefoot/Midfoot System (K100776) Synthes 2.4mm/2.7mm Locking Talus Plate (K071264) Stryker Foot Plating System (K063875)

OCT 08 2013

Device Description:	The system is a collection of plates used for fixation of fractures of the foot and ankle in adults and adolescents (12-21) in which the growth plates have fused or in which the growth plates will not be crossed by the plate system. The complete system includes the following plate types: • 2.4mm/2.7mm Variable Angle Locking Talus Plate • 2.7mm Variable Angle Locking Calcaneal Plate • 2.7mm Variable Angle Locking Anterolateral Calcaneal Plate • 3.5mm Variable Angle Locking Compression Medial Column Fusion Plate The system accepts various screw fixation options such as existing cortical, locking, variable angle locking, low profile, cannulated locking, cannulated conical and metaphyseal screws. The plates are low profile in design and offered in variations of Stainless Steel, Commercially Pure Titanium-Grade 4, and Titanium Alloy (TAN). When used in conjunction with a plate system, the system indications apply to the entire construct, including the screws.

Intended Use

The Synthes 2.7mm and 3.5mm Variable Angle LCP Midfoot/Hindfoot System is indicated for fixation of osteotomies, fusions, fractures, nonunions, malunions and replantations of small bones and small bone fragments in adult and adolescent (12 -21 years) patients, including the foot and ankle, and particularly in osteopenic bone.

The Synthes 3.5mm Low Profile Cortical Screws and the Synthes 3.5mm Cortex Screws are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, hand, radius, ulna, pelvis, tibia, femur, fibula, and foot in adults, and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by the screw fixation.

Substantial Equivalence

Both the Synthes 2.7mm and 3.5mm Variable Angle LCP Midfoot/Hindfoot System and predicate systems have similar indications, design characteristics, materials, and performance characteristics. Fatigue strength testing, as well as engineering analyses were completed for the plates included in the Synthes 2.7mm and 3.5mm Variable Angle LCP Midfoot/Hindfoot System, demonstrating equal to or greater strength in comparison to the predicate devices and constructs.

The subject Synthes 3.5mm Low Profile Cortex and Synthes 3.5mm Cortex Screws share the same indications for use, product technology, and design characteristics. No design changes have been made to the Synthes 3.5mm Cortex and 3.5mm Low Profile cortex screws. No new questions of safety and efficacy are raised as a result of the expanded indications statements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 8, 2013

Synthes (USA) Products, LLC
Ms. Rebecca Reiter
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K131186
Trade/Device Name: Synthes 2.7mm and 3.5mm Variable Angle LCP Midfoot/Hindfoot System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: August 29, 2013
Received: September 3, 2013

Dear Ms. Reiter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin E. Keith

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k): K131186

Device Name: Synthes 2.7mm and 3.5mm Variable Angle LCP Midfoot/Hindfoot System

Indications for Use:

The Synthes 2.7 and 3.5 mm Variable Angle LCP Midfoot/Hindfoot System is indicated for fixation of osteotomies, fusions, fractures, nonunions, malunions and replantations of small bones and small bone fragments in adult and adolescent (12 -21 years) patients, including the foot and ankle, and particularly in osteopenic bone.

The Synthes 3.5mm Low Profile Cortical Screws are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, hand, radius, ulna, pelvis, tibia, femur, fibula, and foot in adults, and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by the screw fixation.

The Synthes 3.5mm Cortex Screws are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, hand, radius, ulna, pelvis, tibia, femur, fibula, and foot in adults, and in both children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by the screw fixation.

Prescription Use _____X_____ (Per 21 CFR 801.109) AND/OR Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices